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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,738	08/16/2006	Shouming Zhong	665690-00004	9844

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EXAMINER	
ANDERSON, HEATHER L	
ART UNIT	**PAPER NUMBER**
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,738	ZHONG ET AL.	
	Examiner	Art Unit	
	Heather Anderson	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/24/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-49 are presented for examination on the merits.

Claim Objections

Claim 28 is objected to because of the following informalities: typographical error improperly inserting a colon into the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising botanical raw materials and botanical drug substances (as defined in the specification on page 2 - i.e., which reasonably read upon extracts thereof) for the treatment of patients with hepatitis C infection does not reasonably provide enablement for a composition comprising botanical ingredients (as defined in the specification on page 2) for the treatment of patients with hepatitis C infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably disclosed/demonstrated compositions comprising botanical raw materials and/or botanical drug substances. However, a composition comprising botanical ingredients is defined as "a component of a botanical drug substance or product that originates from a botanical raw material." This composition as currently claimed could therefore be any possible isolated compound found in any of the plants instantly claimed or even a derivative originating from one of those compounds, which is clearly beyond the scope of the instantly claimed/disclosed invention. While applicants have shown that there are various compounds in each of the cited species of plant that are part of the disclosed composition used for treating hepatitis C, the specification does not give examples for any and all components originating from the instantly claimed botanical raw materials being used to treat hepatitis C.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the instantly claimed composition and practice the instantly claimed method, other than via using a composition comprising botanical raw materials and botanical drug substances (i.e., extracts thereof) for the treatment of patients with hepatitis C infection, as instantly claimed.

All other claims depend directly or indirectly from rejected claims and are therefore, also rejected under 35 U.S.C. 112, first paragraph for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to certain species of herbal ingredients, but Claim 2 is dependent on claim 1 but appears to only be directed to many species within each genus. As this is not further limiting and in fact is broader than Claim 1, claim 2 is rendered vague and indefinite. Claims 43 and 44 have the same problems as claims 1 and 2, respectively.

Furthermore, the specification does not provide any clarification on whether Applicant intended to claim only the species listed in claim 1 or the many species within each genus, as both are referenced throughout. Additionally, all further dependent claims are only directed towards the species with each genus. Therefore, all other claims depend directly or indirectly from rejected claims and are therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

In the interest of compact prosecution, all claims have been assumed to be directed towards the species cited in claim 1.

The phrases appearing in claim 1 and throughout the rest of the claims of "botanical raw materials," "botanical drug substances" and "botanical ingredients," as

defined in the specification, are not commonly used in the herbal arts and appear to be repugnant to the accepted use. As herbal extracts are what is demonstrated in the examples in the specification, the metes and bounds of these terms are not clearly delineated, even with the definitions provided. Therefore, any claims containing any of the above phrases are rendered vague and indefinite. It is suggested that these phrases be amended accordingly so as to recite extracts of the claimed herbal ingredients (as demonstrated).

Claims 45-49 are rendered vague and indefinite due to the fact that they appear to be duplicates of claims 15, 16, 19, and 20, respectively. Although each pair of duplicates depends on slightly different claims, they each pair refer to the same Figures for a TLC chromatic fingerprint or a HPLC fingerprint. Therefore, it is unclear what the differences between these pairs of claims are intended to be.

Claims 41-42 provides for the use of a botanical drug or dietary supplement as claimed in claim 1 in combination with another drug in an amount efficacious to reduce or alleviate the symptoms of hepatitis, particularly hepatitis C, or to support healthy liver function, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

All other claims depend directly or indirectly from rejected claims and are therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 41-42 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (US 6,126,942), Wu (US 6,455,078) and Hammerly (US 2002/0102237).

A composition comprising *Silybum marianum*; *Astragalus membranaceus var. mongholicus* or *Hedysarum polybotrys*; *Salvia miltiorrhiza*, *Salvia bowleyana* or *Salvia przewalskii*; and *Schisandra chinensis* or *Schisandra sphenanthera* is claimed. Dependent claims include percent weights of each component, various aspects of the extract of each component, dosage forms and possible excipients. Additionally, a method of treating a patient to reduce or alleviate the symptoms of hepatitis, particularly hepatitis C, or to support healthy liver function comprising administering to a patient the above-described composition is claimed.

Yang beneficially teaches a composition comprising *Salvia miltiorrhiza* which is used in a method of treating hepatic disorders with viral etiology (see, e.g., the abstract and the entire document). The preferred embodiment of this composition further comprises *Astragalus membranaceus* (see, e.g., column 1, lines 37-41). In Example 3 in column 3, the preferred embodiment is used to treat patients with hepatitis C. It is

known to one of skill in the art the various compounds which are intrinsically present in these herbal ingredients.

Wu beneficially teaches a composition for treating patients with chronic liver disease, such as hepatitis C, comprising Chinese magnoliavine fruit (*Schisandra chinensis*) and milkvetch root (*Astragalus membranaceus*) (see, e.g., column 1, lines 12-23 and entire document). The compounds found in each of these herbal ingredients are found in Table 1 (see, e.g., columns 6-8).

Hammerly beneficially teaches a composition comprising milk thistle (*Silybum marianum*) and an anti-hepatitis medication which is used to treat hepatitis patients (see, e.g., the abstract and the entire document). This composition is used in methods for treating various forms of hepatitis, such as hepatitis C (see, e.g. page 1, paragraphs [0002]-[0003]). The various compounds found in milk thistle are described in paragraph [0017].

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the prior art for the same purpose (i.e., for treating liver disorders, hepatitis C in particular, based upon the well known, demonstrated anti-hepatitis activity such ingredients provide, as fully set forth above) and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art.

This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. In re Kerkhoven, 626 F.2d 846, 850, 205 U.S.P.Q. 1069 (CCPA 1980), In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). The adjustment of particular conventional working conditions (e.g., standardizing each extract to the most effective aspects and/or the most beneficial dosage form and/or determining a suitable effective dosage or percentage of each ingredient) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the cited references as well as the admitted state of the art, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather Anderson whose telephone number is (571)

270-3051. The examiner can normally be reached on Monday-Thursday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry KcKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HLA